

REMARKS

Claims 1, 8, 16 and 24 have been amended. Claim 25 has been canceled. No new matter has been added. Claims 1-9, 11-18, 20-24 and 26 are pending.

Disclaimers Relating to Claim Interpretation and Prosecution History Estoppel

Claims 1, 8, 10, 16 and 24 have been amended, and claims 10, 19 and 25 have been canceled, notwithstanding the belief that these claims were allowable. Except as specifically admitted below, no claim elements have been narrowed. Rather, cosmetic amendments have been made to the claims and to broaden them in view of the cited art. Claims 1, 8, 16 and 24 have been amended solely for the purpose of expediting the patent application process, and the amendments were not necessary for patentability.

Additionally, any reference herein to “the invention” is intended to refer to the specific claim or claims being addressed herein. The claims of this application are intended to stand on their own and are not to be read in light of the prosecution history of any related or unrelated patent or patent application. Furthermore, no arguments in any prosecution history relate to any claim in this application, except for arguments specifically directed to the claim.

Claim Rejections - 35 USC § 112

The Examiner rejected claims 1-26 under 35 USC § 112, first paragraph as failing to comply with the written description requirement. This rejection is respectfully traversed.

First, the Examiner asserted that more specific materials must be identified to show possession of the invention relative the term “monitoring material.” Accordingly, independent claims 1, 16 and 24 have been amended to include the limitation, “wherein the monitoring material is a material selected from the group comprising a naturally weak organism, an attenuated virus, a fungus and a bacteria, wherein the material is tagged with a color.” Thus, the amended claims overcome the rejection.

Second, the Examiner rejected claim 8 under 35 USC § 112, second paragraph as indefinite. In particular, the Examiner required that the term “easily monitored” be clarified. Accordingly, claim 8 has been amended to replace the term “easily monitored” with “visually ascertainable.” Thus, the amended claim overcomes the rejection.

Finally, the Examiner rejected claim 10 under 35 USC § 112, second paragraph as indefinite. Claim 10 has been canceled, rendering the rejection moot.

In sum, it is respectfully requested that the § 112 rejection be withdrawn.

Claim Rejections - 35 USC § 102

The Examiner rejected claims 1, 2, 7-9, 12, 13, 16-18, 21-24 and 26 under 35 USC § 102(b) as anticipated by Medveczky (USP 3,452,135). This rejection is respectfully traversed.

Claims 1, 16 and 24 are independent and all include the limitation “wherein introducing the monitoring material is effected by a process selected from the group comprising injecting under the skin, implantation and transplantation.” In contrast, Medveczky focuses on preparing a urea-based ointment to be percutaneously introduced to the skin for diagnosing allergies (see Medveczky, 1:51-70, 3:1-4). Furthermore, Medveczky solely discloses introduction of an ointment to the skin. Because Medveczky does not disclose introduction of the monitoring material via injection, implantation, or transplantation, Medveczky does not anticipate any of claims 1, 16 or 24.

Additionally, Medveczky’s process is applied for diagnostic purposes (see Medveczky, 1:61-62, 3:1, and 4:1-3). For example, Medveczky’s ointment allows for diagnosis of tuberculosis (see Medveczky, 3:18), TBC allergy (see Medveczky, 4:33), hypersensitivity against egg protein (see Medveczky, 4:45), allergy against *Mycobacterium avium* (see Medveczky, 4:55-56), weak TBC allergy (see Medveczky, 4:69), and *Mycobacterium Minetti* (see Medveczky, 5:8-9). In contrast to Medveczky, claims 1, 16 and 24 are directed to monitoring, not diagnosing. Whereas diagnosing refers to identifying a disease or condition based on symptoms or distinguishing characteristics, the claimed monitoring is limited to simple observation.

More specifically, claims 1, 16 and 24 include the limitation “observing the visually ascertainable indication to thereby visually ascertain the status of a condition, wherein the visually ascertainable indication is a reversible change in color of the monitoring material.” As claimed in all of claims 1, 16 and 24, monitoring of a condition is performed via visual observation of the condition. Because Medveczky’s diagnosing does not disclose the claimed “observing” step, Medveczky does not anticipate any of claims 1, 16 or 24.

In turn, claims 2, 7-9, 12, 13, 17-18, 21, 23, 24 and 26 are not anticipated by Medveczky based on their respective dependency from claims 1 and 16. Given these facts, it is respectfully requested that the § 102(b) rejection in view of Medveczky be withdrawn.

Similarly, the Examiner’s rejections in view of Bender (USP 2,151,495), Burkett (USP 6,830,743), Zeiler (PCT Publication WO 02/39963), and Burns et al. (US Pat. 6,440,388) are respectfully traversed.

Bender is directed to a solution including Guinea Green B and Rose Bengal dyes for application to the teeth to render bacterial plaques visible on teeth (see Bender, 1:1-5). Burkett focuses on a compound which stains dysplastic oral tissue blue when topically applied, via rinsing, when oral tissue includes precancerous or cancerous cells, (see Burkett, 1:5-6, 1:13-15, 13:25-27, 13:42-43). Zeiler focuses on a compound including a copper salt which is topically applied to the top and / or the bottom of a finger or toe nail in order to arrest fungal growth in human nail tissue (see Zeiler, p. 3, lines 12-28). Burns focuses on solutions and suspensions, such as shampoo, cream, lotion or detergent, containing a dye, such as calcofluor white, uvitex 3B, Rylux BA, that fluoresces upon exposure to light (see Burns, Abstract, 3:8-32) for detecting chitin-containing organisms, such as lice, nits mites, ticks and fungal infections (see Burns, 2:6-8). Because none of Bender, Burkett, Zeiler, and Burns discloses the claimed introduction of the monitoring material via injection, implantation, or transplantation, none of the cited references anticipate any of the claims.

Furthermore, none of Bender's staining plaque on teeth, Burkett's preparing novel compounds that stains dysplastic oral tissue, Zeiler's treatment of human nail fungi and Burns's fluorescing discloses the claimed "method of monitoring a condition". Moreover, none of Bender, Burkett, Zeiler and Burns discloses the claimed "observing the visually ascertainable indication to thereby visually ascertain the status of the condition, wherein the visually ascertainable indication is a reversible change in color of the monitoring material" step, none of the cited references anticipates any of the claims. Given these facts, it is respectfully requested that the § 102(b) rejections in view of Bender, Burkett, Zeiler and Burns be withdrawn.

Conclusion

It is submitted, however, that the independent and dependent claims include other significant and substantial recitations which are not disclosed in the cited references. Thus, the claims are also patentable for additional reasons. However, for economy the additional grounds for patentability are not set forth here.

In view of all of the above, it is respectfully submitted that the present application is now in condition for allowance. Reconsideration and reexamination are respectfully requested and allowance at an early date is solicited.

Indeed, the Examiner is invited to call the undersigned attorney to answer any questions or to discuss steps necessary for placing the application in condition for allowance.

Respectfully submitted,

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